UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

IN RE PHARMACEUTICAL INDUSTRY AVERAGE WHOLESALE PRICE LITIGATION	MDL No. 1456 Civil Action No. 01-12257-PBS Judge Patti B. Saris
THIS DOCUMENT RELATES TO: ALL ACTIONS	

DECLARATION OF DIRECT TESTIMONY BY DANIEL L. MCFADDEN, PH.D.

QUALIFICATIONS

1. My name is Daniel L. McFadden. I am the E. Morris Cox Professor of Economics at the University of California, Berkeley, and the Director of the Econometrics Laboratory. I am also a principal at *The Brattle Group*. I received a Bachelor of Science degree in physics, with high distinction, in 1957, and a Ph.D. degree in behavioral science, with specialization in economics, in 1962. Both degrees are from the University of Minnesota.

2. I received the 2000 Nobel Memorial Prize in the Economic Sciences for developing methods and theory used in analyzing how consumers and households make choices from sets of discrete alternatives. My work is now a standard tool in analyzing consumer behavior in a wide variety of markets. It is used to determine how people choose one brand of product over others and how they decide to purchase one type of product over another. Discrete choice modeling is used to understand what features consumers value and how they respond to price changes and to product information. My work also is used commonly in making public policy and regulatory decisions.

3. I received the 2000 Nemmers Prize in Economics, awarded by Northwestern University to recognize "work of lasting significance." In 1975, I received the John Bates Clark

medal, awarded biennially to the economist under 40 judged to have made the greatest contribution to the profession. I also have received the Frisch medal (1986), awarded biennially for the best empirical paper in Econometrica; the Outstanding Paper Award of the American Association of Agricultural Economics (1995), the Richard Stone Prize for the best paper in the Journal of Applied Econometrics (2002), and the Jean-Jacques Laffont Prize (2006) for lifetime achievement.

4. I have served as the James Killian Professor of Economics at the Massachusetts Institute of Technology, the Irving Fisher Research Professor at Yale University, and as a Fairchild Distinguished Scholar at the California Institute of Technology. I have been elected a Fellow of the American Academy of Arts and Sciences and of the National Academy of Science, and have received an honorary LL.D. degree from the University of Chicago, and honorary doctoral degrees from Huazhong University of Science and Technology, the University of London, the University of Montreal, and North Carolina State University. I have served as President of the Econometric Society and as Chairman of the Berkeley Department of Economics. I served as President of the American Economics Association in 2005.

5. My teaching areas include economic theory, econometrics, and statistics at the graduate level. I have published seven books and more than 100 professional papers. My *curriculum vitae,* which is appended to this report as Exhibit 1, includes a list of all my publications within the preceding ten years and my testimony as an expert at trial or in deposition within the preceding four years.

SCOPE OF ENGAGEMENT AND INVESTIGATION

6. I have been asked by counsel for the Track 1 Defendants to review and comment upon the declarations issued by Plaintiffs' economic expert, Dr. Raymond Hartman. In particular, I have been asked to assess the extent to which Dr. Hartman's opinions are consistent with basic economic principles, sound scientific methodology, and the relevant facts of the case.

MARKET TERMINOLOGY

7. In this case, the products in question for the certified classes include drugs sold by defendant pharmaceutical companies and administered to patients by physicians. They are generally referred to as "physician administered drugs." The products in question also include self-administered drugs covered by the durable medical equipment ("DME") provisions of Medicare Part B, such as Albuterol. For this report, physicians administering PADs and pharmacies selling drugs associated with DME are termed "providers," and I use the terms "PADs' or "drugs" generally to refer to all drugs covered by Medicare Part B at issue in this case.

8. PADs move first through a *wholesale* market from pharmaceutical companies to physicians, either directly or through intermediate wholesalers, physician supply houses, or specialty pharmacies. Similarly, self-administered drugs associated with DME move through a wholesale market from pharmaceutical companies to pharmacies. The drugs next move through a *retail* market from providers to patients. Providers are often reimbursed for these drugs by either health care plans or insurers (third party payors, or "TPPs") or by individual patients (for example individual plan beneficiaries or Medicare patients who co-pay a share of the drug costs). Plaintiff TPPs in this case have negotiated contracts with providers whose terms for reimbursement are stated in terms of a discount or premium relative to a published list price for each drug termed the "average wholesale price" or AWP. Providers' average acquisition cost ("AAC") or pharmaceutical companies' average selling price ("ASP") are typically less than the AWP, particularly for drugs with therapeutic or generic competition.

INTRODUCTION

9. The fundamental issue in this case is whether the conduct of the defendant pharmaceutical companies in establishing AWPs unlawfully hampered patients and TPPs in the determination of drug reimbursement rates for providers. Dr. Hartman has opined that retail payors did not understand the relationship between the published AWP of a drug and providers' cost of acquiring the drug. He argues that retail payors would

have been able to negotiate lower drug reimbursement rates, without any offsetting changes in other prices paid for provider services, if they had better information about providers' costs.

10. A threshold economic question presented by Dr. Hartman's theory is whether the prices paid by buyers – patients and TPPs – in the retail market for PADs depend on information and expectations about providers' margins. More specifically, the question in this case is what role, if any, buyers' expectations about the spreads realized by physicians have in determining the prices (reimbursement rates) they pay providers for dispensing or administering drugs.

11. An implication of economic theory is that the realized margins or spreads of sellers in a retail market will affect retail prices. When spreads are high, more sellers will be attracted to this market, and supply will expand in locations with high facility costs or low customer populations where the high spreads are enough to offset the higher costs of providing service. When spreads are low, fewer sellers will be attracted to the market, as other opportunities become relatively more attractive, and services will no longer be supplied in locations with the highest facility costs or lowest customer populations. When there are large numbers of buyers and sellers, the simple economics of supply and demand will determine the balance between the spreads of sellers and the values of buyers. In the case of PADs, entry and exit of providers from the retail market, and the reimbursement rates offered by TPPs to recruit providers into their networks and meet the needs of their clients, are the mechanisms through which market-clearing retail prices would be established.

12. In the simple economics of supply and demand in a retail market, buyer information or expectations about the AAC or spreads of sellers plays no role in the determination of retail prices. It is the actual supply at various prices, determined by actual spreads, not buyers' expectations regarding spreads or supply that determines market-clearing prices. In such a market, information regarding AAC would not confer upon buyers any added power to influence retail prices. Consequently this information would have no interest

or value to buyers, and providing this information (or, alternately, misinformation) would not change their behavior or outcomes.

13. Under some conditions of market structure and conduct of participants, however, buyers and sellers negotiate prices through individual bargaining, rather than price being determined by simple demand and supply. In these circumstances buyers' information and expectations regarding the "walk away" threshold of sellers could influence their ability to bargain, and the prices they attain. In this case, information on AAC could have value to buyers, and they would be expected to actively seek such market intelligence, from their own sources and through purchase, and to use this information in their negotiations with sellers. The economic threshold question then is whether the retail market for PADs has a structure and features consistent with prices negotiated by bargaining between buyers and sellers, so that buyers' expectations may influence retail prices, or whether this market has a structure and features consistent with simple supply and demand, so that buyers' expectations regarding sellers' spreads had no effect on retail prices.

14. If it is found that buyers' expectations regarding sellers' spreads did influence prices paid by payors, it is necessary to determine: 1) how these expectations were affected by the information provided by pharmaceutical companies; 2) how these expectations would change in response to the information that pharmaceutical companies would be required to provide instead in the "but for" world, and 3) what is the relationship between buyers' expectations on sellers' spreads and actual spreads and prices. These determinations would then provide a prediction of retail prices in the "but for" world, and from a comparison of these predicted "but for" prices and the realized "as is" prices, estimates of losses to class members.

15. In summary, to support Dr. Hartman's assumption that payors paid reimbursements for PADs that were elevated due to buyers' expectations on provider spreads that were mislead by pharmaceutical company information on AWPs, the following questions need to be answered:

a. Are the structure and features of the retail market for drugs such that TPPs negotiate with providers to establish prices and would attain an improved bargaining position with accurate information on provider spreads, or are the structure and features of the retail market consistent with simple supply and demand, influenced by realized spreads and the recruitment of providers to TPP provider networks?

b. If prices are determined by bargaining in which prices are influenced by buyer expectations, did pharmaceutical company practices in establishing AWPs unlawfully mislead buyer expectations?

c. If pharmaceutical company practices in establishing AWPs were unlawfully misleading, what conduct would have been required and lawful in the "but for" world.

d. How would buyers' expectations regarding spreads have changed in the "but for" world?

e. What quantitative effect would buyers' expectations in the "but for" world have on retail prices of drugs and on other components of buyers' costs such as administrative fees?

SUMMARY OF OPINIONS

16. Dr. Hartman has either assumed answers to these questions without meaningful scientific analysis, or has drawn unsupported conclusions. Specifically, in the sections that follow I show that:

a. **Dr. Hartman offers no economic analysis of the role of information about provider costs in the market for provider services to TPPs, and he cannot establish that such information has any effect on the prices TPPs must pay to retain providers in their networks.**

Dr. Hartman has not conducted an economic analysis of structure and conduct in the retail market for PADs. He has not tested scientifically his implicit hypothesis that this structure is such that buyers bargain with physicians to determine prices, and can and will bargain more effectively if they have well-informed expectations regarding the spreads that physicians realize. Contrary to his assumptions, there are important undisputed facts about the market for provider services that make Dr. Hartman's theory implausible: (1) Reimbursement rates for drugs are not

individually negotiated with providers by TPPs but are instead established by TPPs for networks of providers, which networks individual providers choose to join or not. (2) TPPs did not attempt to systematically collect information about spreads and no market has developed for information about providers' acquisition costs for drugs, as would be expected if such information were valuable to payors. (3) Most payors, including BCBS of Massachusetts, have not changed their bases for reimbursement away from AWP as the result of additional information on AAC. Those payors, who have moved away from AWP, such as the government, have increased administration fees to offset reductions in ingredient reimbursement rates.

b. If expectations were relevant to reimbursement rates, Dr. Hartman has no reliable evidence of what expectations were, and his 30% yardstick is implausible.

Dr. Hartman offers no empirical evidence of what were the expectations of the class for spreads. Instead, to estimate expectations about spreads, Dr. Hartman relies on the terms of payor reimbursement contracts, which provide only a single reimbursement rate averaged over drugs and over physicians, and on unproven assumptions about the intent of payors to leave providers a margin. But such contracts provide no direct evidence of buyers' expectations about spreads. Dr. Hartman often relies on data that, even under his own interpretation, would provide evidence about average spreads, without providing any information about what the range of spreads might be that make up that average. Further, over a period in which buyer information about the relationship between average acquisition costs and AWPs allegedly increased, spreads generally have not responded to this additional information. This refutes Dr. Hartman's theory that information on wholesale prices influences expectations and that these expectations in turn influence spreads. Dr. Hartman also uses spreads on drugs that do not face competition as a yardstick for payor expectations in circumstances where drugs do face competition. It defies economic theory and common business sense, however, for TPPs to expect that drug prices to providers

would not drop with increases in competition. In addition, many public reports available throughout the class period and before, including reports cited by Dr. Hartman, revealed that spreads on PADs (including on specific drugs at issue in this case) exceeded Dr. Hartman's yardstick. These reports warned also that AWP was not a reliable indicator of acquisition prices. Thus, if TPPs did form expectations regarding spreads based on the AWPs, they did so in careless disregard of public information that AWP was an unreliable guide to AAC and spreads that often exceeded Dr. Hartman's yardstick, particularly when competition increased.

c. If expectations were relevant to reimbursement rates, and even if Dr. Hartman had measured them correctly, there is no reliable evidence about *how* changes in expectations would affect reimbursement rates.

If expectations were relevant to determining spreads, it would be necessary to determine how a change in spreads affects reimbursement rates, just as it would be for other factors that may affect reimbursements. For example, the relative bargaining power between physicians and providers may affect reimbursement rates, as might decisions about the types of contracts and networks payors offer to physicians and consumers. Indeed, Dr. Hartman has conceded that some payors did not pay attention to spreads and would not change their contracting behavior in response to changes in expectations about spreads. Yet, Dr. Hartman simply assumes without any empirical or theoretical basis that changes in expectations would result in dollar-for-dollar changes to reimbursement rates.

d. The but-for world that would be required to avoid liability under Dr. Hartman's analysis could harm competition and consumers.

Dr. Hartman's analysis essentially prohibits any provider from acquiring a drug at a discount from AWP greater than 30%. But he has not provided an economically consistent analysis of how pharmaceutical companies would lawfully meet and respond to the "but for" restrictions that he assumes on pricing or to requirements to publish pricing information. His analysis essentially imposes a "but for" world

in which no drug company could reduce prices to providers if doing so resulted in a spread greater than 30%. He assumes that the alleged fraud outside of Medicare would be cured by reducing AWPs so that spreads over "as is" ASP do not exceed 30% (that is, by making them liable for fraud when spreads exceed 30%). However, in Dr. Hartman's "but for" world, pharmaceutical companies have no incentive to reduce ASP when AWP must be reduced proportionately to maintain the maximum 30% spread. This is because rather than increasing economic incentives to providers by increasing their spread if they purchase the drug in question, the price cuts will reduce economic incentives since the same 30% spread on a lower AWP lowers the dollar margin to the provider. The self-interested and presumably lawful response of the pharmaceutical companies would be to avoid competitive reductions in ASPs, and perhaps to increase AWPs so that the same percentage spread results in a larger dollar margin to the provider. This restriction on competition in the wholesale market would then harm TPPs.

17. I note also that Dr. Hartman's initial report offered the opinion that Medicare would have the same expectations as other payors and therefore that liability arose whenever spreads exceeded 30%. Nonetheless, for those drugs whose spread exceeded 30%, Dr. Hartman calculated damages based on a spread of zero. Dr. Hartman fails to consider the economic consequences of a zero spread on the willingness of physicians to supply PADs under Medicare, or the adjustments in other fees that an economist would anticipate occurring to achieve the availability of service that Medicare is legally required to meet.

18. Moreover, in his supplemental report Dr. Hartman switches his Medicare liability measure so that he finds liability and damages exist *per se* whenever there is any spread at all on the drugs at issue. Dr. Hartman provides no economic basis for the switch in his Medicare liability measure, no economic basis for the Medicare yardstick of zero, and no economic theory to support his Medicare damages calculation. In fact, Dr. Hartman presents both evidence and opinion in his non-Medicare analysis that payors clearly did not expect that AWP plainly meant average provider acquisition cost, which

contradicts the premise of his Medicare analysis. This is especially curious because Dr. Hartman argues also that Medicare's expectations were at least as well informed as those of other payors. He cannot explain how changing the AWP could simultaneously have allowed Medicare reimbursement rates to achieve a zero spread while similar reimbursement rates for other payors for the same drugs would achieve spreads of up to 30%.

19. Even if Dr. Hartman is correct in his legal assumption that Medicare statues require a zero spread, his analysis fails to consider the changes in retail market that would result for Medicare patients if a zero spread were enforced, particularly changes in the willingness of physicians to join the Medicare provider network at a zero spread without some compensating adjustment in other fees.

20. In his supplemental report, Dr. Hartman also changes his measure of ASP without economic justification to include classes of trade that I understand are not at issue in this case. This raises questions about which spreads Dr. Hartman believes payors have in mind and believe are relevant to their reimbursement decisions, and how (or why) he believes reimbursement rates to physicians would change, for example, to reflect discounts given in other classes of trade (such as hospitals).

21. Finally, Dr. Hartman's calculation of damages is affected by arbitrary decisions about how data in his analysis are aggregated.

DR. HARTMAN'S ANALYSIS IS NOT SCIENTIFIC

22. The scientific method in economics, as in other sciences, requires four basic steps:

    a. Specify a clear hypothesis to be tested, which includes identifying critical assumptions and the plausible alternative hypotheses;

    b. Collect relevant and reliable data and information;

    c. Analyze the hypothesis using logic and data, which includes calibrating the hypothesis, estimating unknown parameters, and testing the hypothesis; and

d. Reach reliable and firmly supported conclusions, forecasts, findings, predictions, and inferences based on the previous steps.

23. Dr. Hartman does not follow these basic steps. His analysis, in effect, assumes his conclusions about the existence of the alleged fraud. Dr. Hartman concludes that his critical hypotheses must be true because the evidence that he has collected is, in his judgment, insufficient to reject them. However, sound scientific procedure requires that plausible alternative hypotheses also be considered. The analysis must provide convincing evidence that a critical hypothesis should be accepted and that the plausible alternative hypotheses should be rejected as unlikely or impossible because they conflict with evidence.

24. Dr. Hartman's approach, in contrast to the scientific approach, can be used to adopt the critical hypotheses he finds convenient, even when conflicting hypotheses are at least as well supported by the data. Using this approach, weak or nonexistent data will mean that either a hypothesis or its antithesis could be accepted depending on which is arbitrarily accepted as the candidate hypothesis. To prevent this, the scientifically correct approach is to:

a. Pose a candidate hypothesis that something is true, and then;

b. Accept the candidate hypothesis with confidence only if strong evidence rules out (*i.e.*, rejects) the antithetical or contrary hypothesis.

25. As I discuss in the sections that follow, Dr. Hartman does not offer either a coherent economic framework for his conclusions or any meaningful empirical tests of his core assumptions. Indeed, both economic theory and the empirical and factual evidence in this case support the antithesis of Dr. Hartman's conclusions regarding both liability and the quantum of damages.

DR. HARTMAN OFFERS NO ECONOMIC ANALYSIS OF THE ROLE OF INFORMATION ABOUT PROVIDER COSTS IN THE MARKET FOR PHYSICIAN SERVICES TO TPPS, AND HE CANNOT ESTABLISH THAT SUCH INFORMATION AFFECTS AT ALL THE PRICES TPPS MUST PAY TO RETAIN PHYSICIANS IN THEIR NETWORKS

26. The threshold question raised but not addressed by Dr. Hartman is whether information about spreads to physicians on drugs affects reimbursement rates paid by TPPs. The relationships among list or sticker prices, dealer prices, and consumer prices, which are at the core of this question, are important in many markets, and a general understanding of these relationships is helpful to an understanding of the merits of Dr. Hartman's theory.

ECONOMIC BACKGROUND

27. For purposes of illustration, consider two markets that have list or sticker prices. The first is the market for meals in restaurants and the second is the new car market. The market for restaurant meals has prices determined by simple supply and demand. Customers visit and review the menus of various restaurants, and "vote with their feet" to find the restaurants that give the best value for the price. There is essentially no opportunity to bargain over the price of a meal in a particular restaurant, and customers cannot use information on the wholesale price of foodstuffs or a restaurant's margins to improve the menu prices they face. As a result, customers have no incentive to learn about or to form expectations about the wholesale prices that restaurants face. In effect, the menu prices tell the whole story, and customers influence menu prices only indirectly, through their choices of how often they go to restaurants and which restaurants they chose. The structural feature of the market for restaurant meals is that there are relatively large numbers of restaurants, and there is no effective device that permits restaurants to collude and control prices.

28. The second example is the new car market, where manufacturers post public MSRPs or sticker prices and provide the goods to retailers at private wholesale prices. For autos, wholesale prices to dealers are not usually public, and the spreads between dealer prices and MSRPs can vary across models, with manufacturers offering larger dealer discounts

("dealer incentives") for models that face stiff competition and are not selling well. Customers often negotiate prices for purchases, and in these negotiations, they may be helped by information on dealer prices. They then have an incentive to seek this information, and they use a variety of sources, such as motor magazines and internet services, to obtain it. Because this market intelligence has value for them, they pay to obtain it, by buying magazines or tolerating internet advertising. The structural feature of the new car market that leaves some scope for bargaining is that there are relatively few dealers in an area for cars of a particular brand, and the consequent cost of "voting with your feet" leaves room for dealers to negotiate higher prices from customers who are reluctant to shop around. However, there is sufficient competition between dealerships so that the scope for bargaining is limited.

29. The first question that is raised by these examples is whether, in fact, consumers require or can use information about seller wholesale cost to obtain an acceptable price. It should be clear that competition generally works without consumers requiring such information. When purchasing a good or a service, it is the consumer's retail price that is relevant to the consumer, not the wholesale cost. Of course nearly all retail prices include a markup over the wholesale cost. This is as true for pharmaceuticals as for a restaurant meal. Consumers purchasing a restaurant meal are not harmed because only the retail price is disclosed to them and not the store's wholesale cost of foodstuffs and the farmer's cost of producing these foodstuffs.

30. The reason that consumers usually do not need to know the wholesale cost is that they seek to find the good or service at the lowest total cost to them rather than to find the lowest wholesale margin to the retailer. Competition occurs as competing sellers lower price to attract volume, and consumers benefit because they respond to signals about the price they will pay, not because they understand more about the wholesale cost to the seller. This is why you might, for example, be aware of the price of a dozen eggs or a bottle of soda at your favorite supermarket but have no understanding of (or interest in) the supermarket's cost for those items. Note too that supermarkets will not have a uniform markup on each item they offer, and high markups on some goods may be

offset by low markups on others, but their overall prices and margins will be constrained by competition among supermarkets and other retailers.

31. In some cases, or for some consumers, information about a dealer's cost might be valuable, particularly in situations where the buyer and seller bargain over a price. A second question then arises: what happens if consumers making certain purchases believe they would benefit from information about a supplier's cost? Returning to the car example, some consumers may prefer to limit their search and to negotiate more directly with a single dealer, and such consumers may believe that information about cost is useful to them. In this case, what occurs, consistent also with basic economic principles, is that firms develop and monitor cost information and sell that service to consumers. Quite simply, then, when information is valuable to buyers, buyers seek it out. Of course, there is no guarantee that possessing information (accurate expectations) about a dealer's cost will change his offer price at all. This is particularly true when the dealer has a degree of market power due to limited competing dealerships, for example, or a limited supply of a popular model.

32. A third question is whether consumers would expect that the dealer's cost declines and its profits increase with greater competitive pressures on manufacturers. For example, suppose that gasoline prices increase and manufacturers suddenly find themselves with a large supply of SUVs. Of course, it is well known that increased competitive pressures are likely to lead to lower prices. The manufacturers' incentive to "move market share" is the reason for the reductions in the dealer cost in the first place, because cuts in wholesale prices harm the manufacturer unless it believes that the additional sales justify them. Thus, one would expect that increased competitive pressures on manufacturers will lead to lower wholesale prices, and even consumers who learned nothing about "dealer incentives" would be doubtful that dealer pressure to "move market share" would be the same for a slow-selling SUV as for a popular fuel-efficient alternative during a period of high gasoline prices. The extent to which such lower wholesale prices will be passed on to consumers will similarly depend on the competitive conditions facing the retail market. The retailer with market power, for

example, is more likely to retain the benefits of increased dealer incentives and realize higher margins as a result.

33. To summarize, basic economic theory indicates in general that:

    a. Consumers do not necessarily need to know or use a seller's wholesale cost in order to find the lowest retail price;

    b. Where cost information is valuable, buyers will seek it out, creating incentives for third parties to provide it;

    c. Prices and margins will reflect competitive conditions, with increased competition for a buyer's business leading to lower prices, all else equal; and

    d. If the buyer is a reseller rather than a final consumer, higher margins for the reseller or lower prices to final consumers will result, depending on competitive conditions at retail.

THE ROLE OF SPREADS IN REIMBURSEMENT RATES

34. Providers may acquire drugs directly from manufacturers, and when they do, the price they pay is the manufacturer's ASP, which will depend on the incentives and competitive conditions that face providers when they make decisions to purchase drugs from manufacturers. Alternatively, providers may purchase drugs from intermediaries such as wholesalers, physician supply houses, or specialty pharmacies, and the price paid in these transactions will include a margin or mark-up over ASP to cover the intermediary's costs and profit, the amount of which margin will depend upon competitive conditions facing the intermediary and those facing the provider.

35. Payors at issue in this case have negotiated contracts that reimburse at a discount or premium to AWP. The transactions between payors and providers reflect the incentives and the competitive conditions that face providers when they decide whether to join a payor's insurance network.

36. The "spread" between the reimbursement rate and the provider's acquisition cost is income to the provider. For example, because there is a markup on drugs, physicians face financial incentives to choose therapies based on higher spreads, all else equal. But

note that this is a function of the way the relationship between the payor and the physician is organized and that the incentives exist at every level of AWP.

37. The revenue to pharmaceutical companies is the ASP times the quantity sold. Pharmaceutical companies are concerned with tradeoffs between the selling price they can obtain from their customers, who are intermediaries and providers; the volume of sales; and the willingness of insurers to cover their drugs. Pharmaceutical companies can compete against companies offering therapeutic or generic alternatives by lowering their ASP to gain market share for their products. Competitive pressure on providers arises from the ability of insurance networks to exclude a provider from their coverage and from the prices consumers face for the un-reimbursed portion of drugs and services.

38. The cost of a PAD to the TPP and the patient will reflect the agreed-upon reimbursement rate between a payor and a provider and the co-pay arrangement between the TPP and the patient. The TPPs adjust their reimbursement rates in the retail market to attract and retain providers to their networks and to offer services that attract patients.

39. Similarly, when drugs have therapeutic or generic competition, ASP will be determined by competition to sell to providers. If providers in the retail market experience improvements in their revenue as a result of declines in ASP caused by increased wholesale competition, then the extent to which these will in turn be eroded through competition in the retail market depends on the ease with which providers enter and exit this market, the comparative costs of incumbent physicians and new entrants, and possibly the bargaining position of providers. If providers can enter the retail market with relative ease, and with similar costs to incumbents, then most of the increased revenue resulting from ASP declines will be competed away, with lower prices to patients and TPPs. Some revenues may be dissipated if increased competition among providers pushes practices below optimal scale, in which case they are captured neither by the providers nor the TPPs. On the other hand, if entry by providers is difficult, or entrants face higher costs, then incumbents may be able to retain much of the revenue generated by ASP declines. Thus, there is a large range of possible outcomes in terms

of the extent to which reductions in ASPs result in lower prices to patients and TPPs, depending on the structure of provider supply in the retail market.

40. With respect to the pharmaceutical industry and the role of AWP, an economic analysis of the role of information or expectations about spreads on reimbursement rates must consider: 1) whether in repeated bargaining with multiple providers in successive periods, TPPs acquire direct information on provider resistance to cuts in reimbursement rates for drugs facing therapeutic and generic competition; 2) whether the TPPs ask providers for information about their costs or seek to buy or otherwise acquire this information; and 3) how prices TPPs pay for the services of providers in administering or dispensing drugs in fact have responded over time to changes in information about providers' costs.

41. There are two basic economic models of how the pharmaceutical market might operate. First, TPPs might bargain directly with individual providers over reimbursement rates and providers may possess some degree of market power. In this model, TPP knowledge of provider costs could be used by the TPP to strike a better bargain, all else equal. In one variation of this model, the TPP might have inaccurate information about the provider's costs for drugs. This is the model that Dr. Hartman assumes is reality, and he assumes that inaccurate expectations are due to deception by drug manufacturers in establishing their AWPs. If the retail market for PADs has these characteristics, then it has economic features similar to the new car market, and the questions regarding expectations correspond to questions about the impact of consumer information or misinformation regarding actual dealer invoice costs on the prices they can negotiate for cars.

42. In another variation of this model, the TPP is too rigid institutionally to use information about the provider's drug costs to look after its self-interest. Inconsistently, Dr. Hartman posits this model too in order to explain the observed fact that TPPs have not altered reimbursement rates in response to information about provider costs as his theory predicts they would.

43. In the second model of the pharmaceutical industry, the market for provider services is roughly competitive, with reimbursement rates set by supply. Provider costs affect only providers' profitability and the ability of the marginal provider to stay in business, not reimbursement rates. In this model, knowledge of providers' costs is irrelevant to TPPs. In this alternative, the retail market for PADs would have economic characteristics similar to the market for restaurant meals.

44. Dr. Hartman fails to develop or test either of these economic models, and offers no theory or analysis that explains the role of information about spreads in the market in which TPPs operate.

FACTUAL CONTEXT

45. There are basic facts that are not consistent with Dr. Hartman's fundamental premise that reimbursement rates depend on expectations about spreads. For example:

    a. Reimbursement rates for drugs typically are not negotiated individually with providers by TPPs but are instead established for networks of providers;

    b. No market has developed for information about providers' acquisition costs for drugs, as would be expected if such information were valuable to payors; and

    c. Most payors, including BCBS of Massachusetts, have not changed their bases for reimbursement away from AWP. Those payors who have moved away from AWP, as the government did in 2003, have increased administration fees to offset reductions in ingredient reimbursement rates. I understand also that BCBS of Massachusetts has not changed the level of its reimbursement rates for physician-administered drugs as a result of any information about spreads that might conflict with its prior expectations.

46. Instead of analyzing these phenomena to test the theory presented in his original report, Dr. Hartman imposes upon his theory an entirely new assumption, under which TPPs are so rigid that they cannot act on valuable information to serve their own interests. But as I have explained in academic papers, while economic research does show that under certain circumstances consumers exhibit inertia in established positions, research also shows that where gains are substantial or where choices are made repeatedly (such as in annual contracting), consumers do in fact act to capture those gains and protect

their interests. Dr. Hartman's assumption of institutional rigidity, however, makes it impossible to test scientifically his original theory that TPP's would respond to information that changed their expectations. Moreover, Dr. Hartman's claim that the changes to the federal system constitute a natural experiment about how changes in expectations affected reimbursement rates also fails because while he can establish that Medicare did not change for many years, he cannot show what were its expectations over the class period. Of course, Dr. Hartman has not addressed the issue of what actual losses to TPPs would be if they have misinformed expectations, but are unable to adjust or respond to new information that should alter their expectations. Fundamentally, Dr. Hartman fails to consider the question of the legal obligations of sellers to inform buyers in his "but for" world when these buyers are businesses that fail to protect their own self-interest due to institutional rigidity.

47. Other evidence also suggests that information about spreads is not important to the determination of reimbursement rates. Dyckman & Associates, as cited by Dr. Hartman, conducted a survey in which they asked a sample of TPPs to rank the factors that influence changes in their fee structure. Expectations about spreads were not cited as important in the responses. The three most important reasons given by the TPPs were: 1) "[i]mpact of fee changes on claim costs & premiums," 2) "[i]mpact on plan's ability to maintain an adequate provider network that meets customers' access requirements," and 3) "[p]arity/consistency with competitor fee levels."

48. It is not surprising that payors focus on prices to their customers, prices of competitors, and on whether their reimbursement rates are sufficient to attract the network and membership they seek. What this highlights is that knowledge of spreads is not necessary for competition to lead TPPs to adjust reimbursement rates to reflect the effect of spreads. Mike Beaderstadt, Director of Provider Relations for John Deere Health ("John Deere") explained this competitive process clearly when he testified that his plan set reimbursement rates based on the minimum level necessary to attract and retain providers it wanted in its network. TPPs acting in an economically rational manner will always seek out the lowest reimbursement rate that permits them to assemble the network of providers they seek. That is, TPPs have the incentive to lower

reimbursement rates until the economic incentives of the provider cause the provider to leave the network, independent of the level of AWP or payors' expectations about spreads.

49. Thus, there is no basis in Dr. Hartman's reports or testimony to conclude that information or expectations about spreads affect reimbursement rates. I note also that the behavior of TPPs like BCBS of Massachusetts and John Deere is not consistent with the view that information about provider spreads is highly valuable and determines reimbursement rates.

IF EXPECTATIONS WERE RELEVANT TO REIMBURSEMENT RATES, DR. HARTMAN HAS NO RELIABLE EVIDENCE OF WHAT EXPECTATIONS WERE, AND HIS 30% YARDSTICK IS IMPLAUSIBLE

50. A critical conclusion in Dr. Hartman's analysis is that the spreads expected by all payors for all National Drug Codes (NDCs) and time periods was no more than the actual spread that existed on three single-source innovator drugs during a period of a few years, about 30%. He refers to this level as his "yardstick."

51. For this yardstick to be a correct threshold for liability and damages requires first that as a legal matter, if an AWP is set for a drug that reflects a markup over the physician's cost greater than the amount payors expect such a markup to be, the manufacturer has committed fraud. It requires further three testable assumptions:

    a. That class members expected that the relationship between AWP and ASP for all drugs was governed by a "reasonably predictable amount" which is empirically estimable;

    b. That the "reasonably predictable" spread for any and all drugs facing therapeutic or generic competition was equal to the spread that payors expected for single-source innovator drugs not facing such competition. That is, payors would have to expect that as new competition entered the market, manufacturers did not cut selling prices to physicians; and

    c. That the reasonably predictable spread in no case exceeds 30%.

52. But contrary to basic scientific methods, Dr. Hartman does not test any of these presumptions. I, note too that Dr. Hartman offers as a yardstick what he believes payors expected spreads to be for single-source innovator drugs in periods when they did not face therapeutic or generic competition. As a threshold matter, however, and assuming for the purpose of argument Dr. Hartman's theory of liability, the correct question is not what was the spread for drugs *not* facing therapeutic or generic competition. Rather, the correct question is what did payors actually expect spreads to be for those drugs that *did* face competition - and in particular for the drugs at issue in this case?

53. Although Dr. Hartman testified about how he could develop direct survey evidence on the expectations of class members, he failed to do so. Instead of collecting information directly from class members as he had planned, Dr. Hartman argues instead that class members' self-reported expectations are not reliable. Thus, Dr. Hartman appears to be claiming that he is more knowledgeable about the expectations of payors than the class members themselves. It is curious that Dr. Hartman presented no data on payors' actual market expectations about spreads, yet he claims that: 1) he developed reliable estimates of the beliefs of the plaintiffs about spreads and 2) that these beliefs fell into a small range whose upper limit can be determined and 3) that these beliefs applied to every class member, every NDC, and every time period.

54. Dr. Hartman supports his assumptions using information from three surrogate sources, none of which contains data on the expectations of the class. First, he uses these sources to estimate what actual spreads have been for single-source innovator drugs not facing competition. This leaves untested the propositions that those spreads were understood by class members and that no class member expected that the spread on drugs facing competition exceeded spreads on drugs that did not face competition. More important, a review of each of the data sources shows that if payors relied on this information, or if it reveals their expectations, they would in fact expect spreads on drugs facing therapeutic or generic competition to be higher than spreads on single-source innovator drugs, contrary to Dr. Hartman's critical assumption.

COMPARATOR DRUGS

55. Dr. Hartman's first source of information is data on comparator drugs in periods when they were unaffected by the alleged fraud. He cites NDCs for three such drugs, Zofran, Taxol and Blenoxane, and shows that the annual average spreads on these drugs fall within an 18%-27% range during the years in which they did not face any therapeutic or generic competition. There is no evidence offered that the payors formed expectations based on these three drugs.

56. Dr. Hartman's data for the three drugs, however, shows spreads for both competitive and non-competitive periods. The spreads on the three drugs were significantly higher during periods in which they faced therapeutic or generic competition.

57. Thus, to the extent that actual spreads for these drugs were transparent to payors and informed payor expectations, the spreads indicate that payors would have expected higher spreads during periods of competition. Thus, these data refute his central hypothesis regarding expectations. Of course, if these spreads were not transparent to payors, they could not have informed payor expectations and cannot serve as indicators of expectations.

PUBLICLY AVAILABLE SOURCES

58. A second source of information relied on by Dr. Hartman is publicly available reports that provide information about spreads from physician surveys. Dr. Hartman considered two such reports, the 1992 report of New York State Inspector General (the "OIG survey") and a 2001 report published by the American Society of Clinical Oncologists (ASCO) on Medicare payment reform (the "ASCO report"). As with the comparator drugs, Dr. Hartman offered no evidence that payors relied on these two studies to form their expectations, though he did claim that such documents generally reflect and inform payor expectations.

59. The OIG survey was limited in scope. It covered thirteen chemotherapy drugs, five New York State physicians, two Medicare carriers and a limited time period (January to July 1991). Spreads were averaged by drug, not by NDC. The OIG study warned

readers that it considered only a limited sample of chemotherapy drugs and that the conclusions may not apply to all cases.

60. However, if the OIG study in fact did reveal payor expectations, then it too supports a finding that payors did not expect that AWP was a reliable indicator of AAC and that they did expect spreads for drugs facing therapeutic or generic competition to exceed those for single-source innovator drugs. For example, the 1992 OIG study explicitly states that there is no consistent relationship between AWP and ASP. Moreover, the OIG study presents spreads in excess of 400% for chemotherapy drugs. Note that as a statistical matter, the 400% comes from a limited sample of drugs. If one found such a spread in a small sample, it would be expected that in the entire population of drugs there are some with spreads significantly larger than 400%.

61. The ASCO report cited by Dr. Hartman was a critique of the Medicare payment methods and did not include a new survey of spreads. Nevertheless, it too refutes Dr. Hartman's key hypothesis, that class members expected the same spreads on all drugs and time periods, because the study noted that AWP was not a reliable indicator of acquisition prices.

62. These studies clearly show that competition increases spreads to levels well above 30%, and it is not appropriate to refer to them, as Dr. Hartman does, only to determine the spreads on drugs that do not face competition. Other public studies conducted by the OIG but not cited by Dr. Hartman also show that PADs had spreads in excess of 30% and that AWP was not a reliable indicator of acquisition costs.

CONTRACTUAL REIMBURSEMENT RATES

63. As his third source, Dr. Hartman argues that the range of payor expectations about the spreads for any single NDC can be determined by a review of the range of negotiated reimbursement rates between payors and physicians. He suggests there are two ways that such contracts reveal payor expectations. First, Dr. Hartman notes that the lowest reimbursement rate he identified for PADs was AWP -15% (so that corresponding spreads over ASP would be somewhat more that 15%). Dr. Hartman then argues that

since payors would intend to leave "some margin" for providers, contract reimbursement rates for the most favorably positioned payors are consistent with his conclusion that expectations for payor spreads could not exceed 30%. He states also that his review of contracts demonstrates that TPPs have negotiated reimbursements for PADs in a range of AWP ± 15%, so that the maximum difference in reimbursement rates between any two payors is 30%. The suggestion appears to be that this 30% variability in reimbursement rates reflects the variability in payor expectations.

64. In his report, however, Dr. Hartman presents only four contracts covering two payors. He says that a similar range is found by the MedPAC report of 2003 which, using data for 2002, showed that TPPs reimburse PADs on average of 97.5% of AWP (*i.e.*, AWP – 2.5%) with the range being 85% to 115%.

65. Dr. Hartman's data on reimbursement rates is limited and his sample does not define the population of contracts that existed throughout the class period. Thus, he cannot conclude statistically that the range of reimbursement rates for any payor did not exceed 30% during the class period. Indeed, statistics indicate that the range of the population of contracts would indeed exceed the range of the sample. Thus, Dr. Hartman should have concluded that the contract reimbursement rates do not provide support for the proposition that payor expectations of spreads never exceeded 30%.

66. More fundamentally, Dr. Hartman's theory that the reimbursement contracts "reveal expectations" about spreads for drugs facing therapeutic or generic competition is incorrect.

67. First, the contracts he reports apply a common reimbursement rate to a variety of drugs. They do not provide any information about what was the expected maximum spread for any drug or group of drugs. As a result, the reimbursement contracts tell us nothing about whether payors expected a 30% limit to the range in the spread for all NDCs and all years.

68. Second, the reimbursement rates incorporate many other factors, as acknowledged by Dr. Hartman. Once other factors are considered, an expected spread of 100% on ASP

(that is, an ASP that is 50% of the AWP) can just as easily lead to a discount of 15% from an AWP, on average, as an expected spread of 30%. Payors may knowingly negotiate to permit physicians to retain some portion of the spread larger than the approximate margin assumed by Dr. Hartman. For example, the level of margin that the payors must leave to the providers is determined by their relative market power as well as the optimal composition of the network that payors wish to achieve. Thus, if the provider has significant market power and/or the payor must leave a generous margin to the provider in order to attract the provider to its network, it may agree to a contract reimbursing at a discount of 15% from an AWP even though the payor's expectation was that the physician received an average discount of 50% (or higher) of AWP from the manufacturer.

OTHER FACTORS AND DATA

69. Dr. Hartman also has failed to test whether the market power of doctors is an "intervening factor" as noted by the Court. This is curious because Dr. Hartman's has testified that at least some of the spread income is not due to the alleged fraud but resides in the bargaining position of the physicians.

70. Dr. Hartman could have tested his theory that contracts reflect expectations about reimbursement rates. If the theory were valid, one would expect statistically significant decreases in reimbursement rates over the class period as information about spreads allegedly became more wide spread. In fact, Dr. Hartman does not observe a large drop in reimbursement rates for contracts between payors and physician groups over time, which suggests his hypothesis is incorrect. He notes too that his review of the contract data suggests that contracts were being negotiated at a discount of 15% to 20% from AWP even though contemporaneously available reports on drug prices suggested much larger spreads of 60% to 80%.

71. Other data also are inconsistent with the theory that reimbursement rates would change in response to information about spreads. For example, plaintiff Blue Cross Blue Shield of Massachusetts's (BCBSMA) Mr. Mulrey testified that BCBSMA estimated it could save millions annually by switching to ASP-based pricing. Despite those savings,

BCBSMA has decided to leave its reimbursement rate for PADs unchanged at AWP-5%. Presumably, its expectations about spreads presently are relatively accurate, yet reimbursement rates are unchanged. Mr. Mulrey noted that one consideration could be keeping providers in its network.

72. Data that show reimbursement rates have not changed over time in response to new information about spreads should have caused Dr. Hartman to reject his theory. He has no reliable evidence to confirm his "market expectations yardstick" for liability. This same problem causes his damage theory to be divorced from any reliable and contemporaneous evidence on expectations, and we are left only with Dr. Hartman's assertion that his theories will be supported by changing reimbursement rates at some future time.

73. Beyond the fact that there was public information indicating that spreads were in excess of 30% and that AWP was not a reliable indicator or acquisition costs, Dr. Hartman's theory that payors would not expect spreads to increase as competition for a new drug enters is not plausible as a matter of economic logic.

74. Suppose, for example, that payors observe that the AWP for a single-source innovator drug remains the same or increases over time (AWPs clearly are visible to payors through claims data and published sources). Over that same period, payors also can observe that therapeutic competitors enter and later that generic competitors enter. Dr. Hartman's assumption requires that payors did not expect that selling prices would drop in the face of such new competition and that, indeed, if the AWP increased over time, the selling price must have increased correspondingly. He provides no evidence that payors lacked the simple intuition that prices would decline once a monopoly provider faced competition, as would be expected in virtually any market.

75. Dr. Hartman himself argues and cites evidence that it was widely understood that ASPs for drugs fell dramatically as generic competition entered the market. He states, however, that this widely understood expectation applied only to self-administered drugs because physician-administered drugs were "less scrutinized or understood." Even if true, the lack of information does not compel or even support the conclusion that

payors expected their spreads to be the same as monopoly drugs and relied on that expectation in their negotiations. It is also curious that Dr. Hartman ignores that higher spreads were well-known even for the generic, self-administered drugs at issue in this case. For example, I understand that Albuterol manufactured by Warrick, a drug for which Dr. Hartman finds liability and damages using his yardstick, was generic and primarily self-administered.

76. Instead of testing the critical hypothesized relationship between expectations and reimbursement rates, Dr. Hartman again simply assumed his conclusion that reimbursement rates would change with changes in expectations when he rejects direct evidence about expectations as unreliable unless the evidence also leads to changes in reimbursement rates.

77. I conclude that Dr. Hartman offers no evidence that the class members had expectations about spreads that informed their reimbursement rates, and if they did, no evidence of what any of these expectations were. He does not offer any evidence that any expectations of spreads fell into a relatively narrow range less than 30%, and to the extent they are relevant, the data cited in his reports, as well as other public data, contradict his conclusion.

IF EXPECTATIONS WERE RELEVANT TO REIMBURSEMENT RATES, AND EVEN IF DR. HARTMAN HAD MEASURED THEM CORRECTLY, THERE IS NO RELIABLE EVIDENCE ABOUT HOW CHANGES IN EXPECTATIONS WOULD AFFECT REIMBURSEMENT RATES. AS A RESULT, HIS DAMAGES ESTIMATES ARE OVERSTATED

78. The fundamental premise of Dr. Hartman's liability analysis is that pharmaceutical companies raised spreads to increase sales volumes and that payors were ignorant of these spreads. Dr. Hartman argues that had payors known about the spreads, they would have adjusted reimbursement rates in response to capture for themselves spreads exceeding the 30% "yardstick." I show that that conclusion is unsupported, inconsistent with economics, and overstates any damages from the alleged fraud.

NON-MEDICARE PAYORS

79. Dr. Hartman applies one formula to calculate damages for all class members, all drug categories, and at all times during the damage period for non-Medicare claims. Damages are based on the product of the reimbursement rate and the difference in spreads that result from the actual AWP and the but-for AWP, (*i.e.*, the AWP that would have been observed but for the alleged fraud):

*Damages = reimbursement rate * (Actual Spread – 30% But-for Spread) * ASP * Quantity*

80. The only variable that is different between the but-for and the as-is world in Dr. Hartman's damages formula is the AWP. All other variables retain the same values. The but-for AWPs for each NDC are estimated by reference to actual ASPs and incorporate the maximum spread that Dr. Hartman assumes payors would expect across all drugs (30%). The reimbursement rate, which is the mechanism by which Dr. Hartman argued payors would adjust to information about spreads (and therefore the variable that would change in the but-for world), is unchanged.

81. Contrary to Dr. Hartman's assumption, pharmaceutical companies would not adjust their AWPs downward in his but-for world to match payor expectations because pharmaceutical companies in the but-for world will face the same basic economic incentives to increase spreads as they do in the real world.

82. The only way that Dr. Hartman's but-for spreads would exist for drugs facing competition is if they were mandated legally. In that scenario, liability for fraud and damages would arise *per se* from price competition, irrespective of plaintiff expectations, and there is no causal link between expectations and the alleged fraud. Even under that scenario, Dr. Hartman's conclusions are incorrect. AWP and ASP will not drop as Dr. Hartman predicts in the face of new competition, and instead both AWP and ASP could be *higher* as a result of the incentives that would face drug companies and physicians if spreads were constrained legally not to exceed 30%.

AWPs Would Not Drop in Dr. Hartman's But-for World

83. If fraud is defined in terms of a discrepancy between actual spreads and expectations, it can be cured by informing and thereby changing expectations rather than by conforming spreads to some defined limit. For example, drug companies could announce that published AWP bears no "reasonably predictable" relationship to ASP. If required, drug companies might publish more information about specific spreads.

84. The economic incentive to change spreads to attract volume does not arise from the alleged hidden nature of the spreads from the point of view of payors. It arises because cutting price and increasing spreads make drugs more attractive economically to the physicians and pharmacies that provide them. Thus, even if payors knew that there was no predictable relationship between AWP and ASP for all drugs, and even if spreads or ASPs were published, competition for sales to providers would exist as an incentive to increase spreads. This is in fact the normal competitive process of firms cutting prices in response to competition in order to gain a temporary market share advantage.

85. If fraud depends on expectations, the likely competitive result would be to provide whatever minimum information cures the inaccurate expectations rather than to drop AWP. Even in the fraud-free world, pharmaceutical companies will continue to face competitive pressure to cut prices and increase spreads.

86. Dr. Hartman's analysis therefore requires that fraud be independent of expectations. Rather than define fraud based on expectations, his damages analysis requires that fraud occur *per se* whenever spreads exceed 30%, regardless of payor expectations.

ASPs, And Possibly AWPs, Would Increase If Spreads Are Capped

87. The *per se* description of fraud is the only logical way to interpret the yardsticks selected by Dr. Hartman. Specifically, the yardsticks attempt to identify what spreads would be absent competition rather than what expectations of the class members actually were in the as-is world and how they affected reimbursement rates.

88. As a result, in describing fraud as he construes it in his liability and damages model, Dr. Hartman uses the concept of "expectations" to refer not to the actual expectations of the class members, but rather to what expectations would be if drug companies never competed by increasing spreads and spreads were kept at levels consistent with those for drugs not facing competition.

89. If that understanding of fraud is accepted, the relevant question then becomes whether ASPs would in fact drop to the levels actually observed in the world in a world where spreads are capped at 30%. ASPs dropped in the actual world because competition pressured drug companies to cut prices and increase spreads to physicians. Would such price cuts occur if drug companies were legally required to limit spreads to 30%? The answer clearly is "no" because companies that cut prices in order to increase volume ("to move market share") would have no reason to cut them when doing so would not move market share.

90. If spreads beyond the initial level set for single-source innovator drugs are deemed to be illegal, there would be no incentive to cut price as competition enters. Capping spreads at 30% will reduce price competition because it will eliminate any incentive to reduce ASPs from the monopoly level as competition enters. This contradicts Dr. Hartman's position that the ASP will not change in the but-for world.

91. Thus, Dr. Hartman's damages calculations are inconsistent both with his theory of fraud and with basic economic principles and are overstated.

Reimbursement Rates Would Not Decrease to Create the Damages in Dr. Hartman's But-For World

92. The question arises whether Dr. Hartman's damages formula is not to be taken literally but is instead short hand for an adjustment that would take place through changes in reimbursement rates. Again, the answer is "no."

93. Different payors will have different interest and ability to respond to information concerning spreads. For example, Dr. Hartman has argued that some TPPs did not respond at all to information about spreads. If plaintiffs would have acted no differently

even if they had been aware of a difference between the actual spreads and the expected spreads, Dr. Hartman should have reflected this in his damages analysis.

94. Dr. Hartman admits that TPPs vary not only in their knowledge of spreads, but also in their negotiating skills, market power, and other factors affecting negotiated reimbursement rates. Thus, for example, some physician groups may have sufficient bargaining power to keep incomes unaffected by changes in expectations about spreads. Dr. Hartman himself appears to have acknowledged this when he stated in his rebuttal declaration that to recover the full effect of the spreads above his yardstick, a payor would need not only information about the spread, but market power over the physician as well.

95. This being so, one would not expect that providers could invariably be forced to pass on all realized spreads in excess of 30% through renegotiated reimbursement rates. A correct damages analysis would require a determination of each 'TPP's expectations during the class period, how they would differ absent the alleged fraud, and how those differences would be reflected in reimbursement rates negotiated with physicians given the variety of factors that enter into the reimbursement determination.

96. Thus, Dr. Hartman cannot determine how different expectations would affect (if at all) reimbursement rates, and the damage estimate presented by Dr. Hartman overstates damages even if one assumes that the yardstick correctly measures expectations in the but-for world.

MEDICARE

97. For Medicare, there is simply no relationship in Dr. Hartman's analysis between a liability claim arising from plaintiffs' expectations of spreads and his measure of damages. Instead, Dr. Hartman relies on a legal interpretation of various statutes, even though Dr. Hartman previously claimed no expertise in Medicare reimbursement.

98. Dr. Hartman changed his theory of liability for Medicare between the filing of his initial report on liability and damages and the filing of his supplement to that report. In his

initial report, he applied the same 30% expectations yardstick to determine liability that was applied to other payors. He testified that he believed the expectations for Medicare would be the same as for other payors or that Medicare may have been more informed that private payors. Despite that belief, which he applied for purposes of liability, his damages analysis for Medicare was based on a but-for spread of zero. Thus, with respect to single-source drugs reimbursed under Medicare Part B until 2004, if a drug had an spread of less than 30%, Dr. Hartman argued it should have been reimbursed on the basis of the spread as it was. If a drug had a spread of more than 30%, Dr. Hartman assumed that the drug should have been billed to Medicare and/or reimbursed at the provider's acquisition cost, without any spread.

99. Mechanically, Dr. Hartman achieves this result by leaving all parameters unchanged from the as-is world and altering the but-for AWP. Of course, it is mathematically impossible to establish the but-for AWP equal to ASP (zero spread) to satisfy Dr. Hartman's claimed legal requirement for Medicare, while setting the but-for AWP at a 30% spread over ASP to satisfy the alleged "market expectation" of the private sector. Thus, there does not exist any AWP that would be consistent with both Dr. Hartman's Medicare and his non-Medicare measures of liability.

100. Because it is based on a legal analysis rather than economics, I make only some limited observations about Dr. Hartman's Medicare damages theory, focusing for simplicity on his analysis of single-source drugs. First, Dr. Hartman disavows the notion that he is calculating a fraud-free AWP in his Medicare damage claims. Second, Dr. Hartman's damages model assumes that PADs would be reimbursed at ASP. If this means that all payors would be reimbursed at the average price (as opposed to each physician being reimbursed based on her individual acquisition cost), the implication is that half of the PADs are administered at a loss. This would create adverse effects on incentives to provide services to Medicare patients.

101. Finally, I note that in all cases, Dr. Hartman's damages models are incomplete. This is because Dr. Hartman ignores the impact of changes in drug reimbursement rates on related service prices. To the extent that payors or providers are concerned about the

total payments to a provider for the combined drug and the care (or dispensing service) associated with administering that drug, changes in the reimbursement rate on drugs may have to be offset by changes in fees demanded for the related service. For example, I understand that the recent changes to Medicare Part B reimbursement to reflect ASP-based pricing for drugs in the Medicare Modernization Act have been accompanied by substantial increases in payments for drug administration. Similarly, Mr. Mulrey of BCBSMA testified that when he analyzed a switch to ASP-based pricing for PADs, which was not implemented, he incorporated in that analysis an increase on administration fees to physicians. Dr. Hartman testified that he does not know whether such cross-subsidization was necessary as an economic matter, but takes his position based on a legal instruction.

THE BUT-FOR WORLD REQUIRED TO AVOID LIABILITY UNDER DR. HARTMAN'S ANALYSIS COULD HARM COMPETITION AND CONSUMERS

102. In either version of Dr. Hartman's but-for world, where either expectations are informed or spreads are legally capped at 30%, how would pharmaceutical companies compete for business? In either version of Dr. Hartman's but-for world, there likely would be important, harmful consequences for competition and consumers.

103. Requiring public disclosure of wholesale prices is potentially anticompetitive. The well-recognized argument is this: If wholesale prices are not public, then suppliers can cut prices selectively to gain market share, at least temporarily. This is the normal competitive process, and depending on the competitive conditions among retailers, may lead to lower prices for consumers. However, if wholesale price cuts must be made public, they invite immediate responses from rivals that eliminate the temporary competitive advantage conferred by the price incentive. This in turn removes the incentive to offer the selective cut.

104. The general economic proposition is that for competition to work there must be enough private information and opportunities for small extra profits to create effective incentives. As word gets out, other manufacturers observe losses of market share and

must cut prices to meet competition. As the process continues competition at retail will force pass-throughs to customers, depending on the strength of competition.

105. Note too that if customers require cost information to get the best price, it is the dealer who has the incentive to withhold that information, not the manufacturer. The obligation might best be placed on the dealer to disclose its specific incentives and costs for the specific vehicle rather than to require the manufacturer to post a general average wholesale price over a broad group of dealers and with a lag.

106. Dr. Hartman's *per se* rule makes little sense as public policy. In his model, increased spreads that are expected by payors are recovered from physicians in higher reimbursement discounts. In that model, class members benefit from increased spreads when they bargain for better terms with providers. But if spreads are legally capped at 30%, drug companies have no incentive to lower ASPs to the extent they did in the actual world. Acquisition prices would be higher as a result. The incentive would be to raise both ASP and AWP (*i.e.*, 30% of a higher ASP), which would increase payor costs. A cap on spreads (if it actually constrained provider incentives as Dr. Hartman alleges) may at the margin lead to exit of some physicians, reducing patient access, which could potentially harm consumers.

107. Based on observation of regulated industries, I conclude that when spreads are capped, competition will occur in other dimensions, such as added advertising or added sales staff, which increase costs but do not typically pass through as benefits to retail consumers.

COMMENTS ON DR. HARTMAN'S CALCULATIONS TO APPLY HIS THEORY

108. I conclude with some limited observations on the calculations Dr. Hartman made to apply his theory in estimating damages. I show that important elements of the analysis are based on arbitrary assumptions about aggregation and ASPs.

AGGREGATION ISSUES

109. In his initial declaration on class certification, Dr. Hartman stated that the calculation of spreads and yardsticks was to be performed by time period, by drug and/or by NDC, and he would make a final determination about these issues once the final data were produced.[1] In his report on liability and damages, Dr. Hartman performed the damage calculations at the NDC-year level but did not provide any justification for why an analysis at this level was an appropriate measure of expectations. In particular, Dr. Hartman did not conduct any tests to validate the view that payors formed expectations at the NDC level and that these expectations were updated each calendar year. As shown below, Dr. Hartman's method of aggregation is arbitrary and likely overstates non-Medicare damages by excluding data points that show spreads below his yardstick level of 30%.

110. The problem with Dr. Hartman's approach is apparent when one examines his pattern of spreads and damages across the time period considered. In several cases, an NDC goes in and out of liability due to the spreads fluctuating above and below the 30% threshold.[2] Dr. Hartman has not offered any explanation for these patterns.

111. Given these patterns in the data, Dr. Hartman should have considered alternate methods of aggregating data. For example, he could have aggregated across all time periods by NDC or across all time periods by drug. Such aggregations would be more consistent with Dr. Hartman's assumption that the payors' expectations did not change during the class period and that response to new information was characterized by extremely long lags.

112. Table 1 illustrates that Dr. Hartman's damages are sensitive to the way the data is aggregated. Aggregating across time periods for an NDC or across NDCs and periods for a drug, for example, lowers the calculated damages. Column 1 of Panel A shows the Sub-Class 3 aggregate damages as computed by Dr. Hartman for NDCs for which he

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1 Hartman Declaration, September 04, 2004, p. 20.

2 For example, Procrit 10,000 U/ML, Multidos shows spreads of 27.0%, 45.2%, 34.9%, 29.9% from 1995 to 1998; Intron A INJ 25MIU HSA FREE shows spreads of 23.9%, 30.5%, 35.9%, 28.6% from 1999 to 2002.

finds liability but that had spreads less than 30% in some years.[3] Column 2 shows the results if damages are computed by aggregating across all time periods for each NDC. These damages are computed by summing Dr. Hartman's damages across time for each NDC and subtracting "negative" damages from the total. The resulting estimates are significantly lower for certain NDCs. For example, the damages are more than halved, going down from $0.44 million to $0.20 million for an NDC of Taxol. Panel B shows the results if damages are computed by aggregating across time periods and NDCs for certain drugs.[4] This approach yields even lower figures with Procrit and Introl showing zero damages against a 30% yardstick. These calculations suggest that it is important to determine the appropriate level of aggregation before damages can be calculated.

[3] Note that the table does not include damages for years in which Hartman extrapolated data to fill in the figures for years in which he had missing data; thus, the damages attributed to Dr. Hartman's methodology (in column 1) are different from the totals listed in his report.

[4] These damages are computed by summing Dr. Hartman's damages across time and NDCs for each drug and subtracting "negative" damages from the total. The negative damages are obtained for those years and NDCs in which the spread for is less than 30%. This approach is equivalent to estimating a revenue weighted-average spread for each drug and then applying the weighted-spread to all years and NDCs of that drug. If the weighted-spread is less than 30% for any drug, damages are set to zero for that drug.

Table 1: Summary of Damages Using Alternate Methods of Aggregation

			Non-Medicare, TPPs and Consumers (Massachusetts– Sub-Class 3)	
Company	**Drug**	**NDC**	**Dr. Hartman's Estimates (1)**	**Aggregation Across Years/Across NDCs and Years (2)**
Panel A				
Bristol Myers-Squibb	Taxol	00015347911	$436,107	$199,831
Johnson & Johnson	Procrit	59676032001	$264,112	$163,413
Schering-Plough	Intron	00085053901	$176,536	$123,489
Panel B				
Bristol Myers-Squibb	Taxol	All	$725,791	$257,524
Johnson & Johnson	Procrit	All	$857,924	$0
Schering-Plough	Intron	All	$998,399	$0

Notes and Sources:

(1) Dr. Hartman's estimates are the damages he calculated in his December 15, 2005 Declaration. The damages will not match those listed in the report because the table does not include Dr. Hartman's extrapolation to years not covered in the data.

(2) These damages are computed by summing Dr. Hartman's damages across time and NDCs for each drug and subtracting "negative" damages from the total. The negative damages are obtained for those years and NDCs in which the spread for is less than 30%.

COMPUTATION OF ASP

113. In his supplemental declaration of February 2006, Dr. Hartman revises his computation of ASP by including sales to hospitals and HMOs.[5] The result is to increase significantly the spreads on many drugs over his December 15, 2005 calculations. Consequently, many NDCs that were below the 30% liability threshold in the earlier Declaration crossed the threshold in the supplemental Declaration. Table 2 shows examples of such NDCs.

114. The substantial changes in the ASPs and spreads cast doubt on Dr. Hartman's liability theory and damage methodology. In particular, the results in Table 2 undermine Dr. Hartman's key liability assumption that the AWP is a signal for ASP calculated for PADs in this proceeding. It is evident that the same AWP is associated with several different ASPs; the ASPs for hospitals and HMOs are lower than those for physicians in many cases. Calculating a single ASP over all classes of trade solves the multiple-ASP problem at the cost of creating another problem for the damage calculation. If there is a significant difference in ASPs by class of trade as the patterns in Table 2 suggest, it is not justifiable for Dr. Hartman to include hospitals and HMOs in the calculations for ASP in his damage calculation. The mixing of the classes of trades leads to an overestimation of damages at the aggregate level for PADs, because class members are being awarded damages due to larger spreads to non-class members (hospitals and HMOs). Table 2, in fact, shows that calculating damages based on the revised ASPs will award damages to class members for certain drugs even though prices to their providers do not create spreads that exceed their expectations as measured by the Hartman "yardstick."

[5] For example, for BMS Dr. Hartman includes data on civilian hospitals, community health care clinics, and various types of HMOs. These data were not included in the calculation of ASP in the December 15, 2005 Declaration.

Table 2: ASPs and Spread in Supplemental vs. Original Declarations

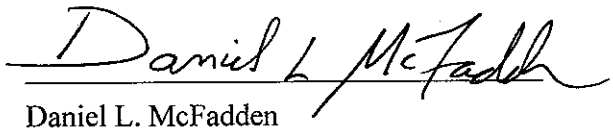
Drug	NDC	Year	Original ASP ($)	Original Spread (%)	New ASP ($)	New Spread (%)
Cytoxan	00015054812	1998	41.14	25.01	19.40	165.08
Taxol	00015347520	2000	146.10	25.00	135.11	35.17
Vepesid	00015309530	1996	108.00	26.38	66.82	104.26
Kytril	00029415105	1999	694.43	29.16	634.87	41.27
Lanoxin	00173026035	1997	79.79	20.69	55.88	72.34
Ventolin	00173038558	1992	12.23	21.52	9.88	50.42
Zofran	00173044702	1999	2,025.16	25.34	1,799.71	41.04
Intron	00085057106	1997	496.90	26.82	394.69	59.66
Proventil	00085020901	1991	26.39	18.00	21.70	43.52

Notes and Sources:

(1) Original ASP and Spreads source: Hartman workbooks "X Liability Damages.xls", where X is the respective defendant.

(2) New ASP and Spreads source: Hartman workbooks "X Liability Damages - Revised ASP.xls", where X is the respective defendant.

I declare under penalty of perjury that the foregoing is true and correct. Executed on November 10, 2006.



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